

## § 177.2210

## 21 CFR Ch. I (4–1–13 Edition)

2959, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(3) The basic polymer or food-contact article described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields net chloroform-soluble extractives in each extracting solvent not to exceed .08 milligram per square centimeter (0.5 milligram per square inch) of food-contact surface when tested by the methods described in § 176.170(d). If the finished food-contact article is itself the subject of a regulation in parts 174 through 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by the regulation.

[49 FR 29578, July 23, 1984]

### Subpart C—Substances for Use Only as Components of Articles Intended for Repeated Use

#### § 177.2210 Ethylene polymer, chlorosulfonated.

Ethylene polymer, chlorosulfonated as identified in this section may be safely used as an article or component of articles intended for use in contact with food, subject to the provisions of this section.

(a) Ethylene polymer, chlorosulfonated is produced by chlorosulfonation of a carbon tetrachloride solution of polyethylene with chlorine and sulfuryl chloride.

(b) Ethylene polymer, chlorosulfonated shall meet the following specifications:

(1) Chlorine not to exceed 25 percent by weight.

(2) Sulfur not to exceed 1.15 percent by weight.

(3) Molecular weight is in the range of 95,000 to 125,000.

Methods for the specifications in this paragraph (b), titled “Chlorine and Bromine—Coulometric Titration Method by Aminco Chloridometer,” “Hypolon® Synthetic Rubber—Determination of Sulfur by Parr Bomb,” and ASTM method D2857-70 (Reapproved 1977), “Standard Test Method for Dilute Solution Viscosity of Polymers,” are incorporated by reference. Copies of the ASTM method may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959. Copies of the other two methods are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Copies of all three methods may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) The additive is used as the article, or a component of articles, intended for use as liners and covers for reservoirs intended for the storage of water for drinking purposes.

(d) Substances permitted by § 177.2600 may be employed in the preparation of ethylene polymers, chlorosulfonated, subject to any limitations prescribed therein.

(e) The finished ethylene copolymers, chlorosulfonated shall conform to § 177.2600(e) and (g).

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10111, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

#### § 177.2250 Filters, microporous polymeric.

Microporous polymeric filters identified in paragraph (a) of this section may be safely used, subject to the provisions of this section, to remove particles of insoluble matter in producing, manufacturing, processing, and preparing bulk quantities of liquid food.

(a) Microporous polymeric filters consist of a suitably permeable, continuous, polymeric matrix of polyvinyl chloride, vinyl chloride-propylene, or vinyl chloride-vinyl acetate, in which

finely divided silicon dioxide is embedded. Cyclohexanone may be used as a solvent in the production of the filters.

(b) Any substance employed in the production of microporous polymeric filters that is the subject of a regulation in parts 170 through 189 of this chapter must conform with any specification in such regulation.

(c) Cyclohexanone when used as a solvent in the production of the filters shall not exceed 0.35 percent by weight of the microporous polymeric filters.

(d) The microporous polymeric filters may be colored with colorants used in accordance with §178.3297 of this chapter.

(e) The temperature of food being processed through the microporous polymeric filters shall not exceed 180 °F.

(f) The microporous polymeric filters shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(g) To assure safe use of the microporous polymeric filters, the label or labeling shall include adequate directions for a pre-use treatment, consisting of washing with a minimum of 2 gallons of potable water at a temperature of 180 °F for each square foot of filter, prior to the filter's first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 56 FR 42933, Aug. 30, 1991]

#### § 177.2260 Filters, resin-bonded.

Resin-bonded filters may be safely used in producing, manufacturing, processing, and preparing food, subject to the provisions of this section.

(a) Resin-bonded filters are prepared from natural or synthetic fibers to which have been added substances required in their preparation and finishing, and which are bonded with resins prepared by condensation or polymerization of resin-forming materials, together with adjuvant substances required in their preparation, application, and curing.

(b) The quantity of any substance employed in the production of the resin-bonded filter does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of resin-bonded filters that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of resin-bonded filters include the following, subject to any limitations provided:

##### LIST OF SUBSTANCES AND LIMITATIONS

###### (1) *Fibers:*

Cellulose pulp.

Cotton.

Nylon. (From nylon resins complying with the provisions of applicable regulations in subchapter B of this chapter.

Polyethylene terephthalate complying in composition with the provisions of §177.1630; for use in inline filtration only as provided for in paragraphs (e) and (f) of this section.

Rayon (viscose).

###### (2) *Substances employed in fiber finishing:*

BHT.

Butyl (or isobutyl) palmitate or stearate.

2,5-Di-*tert*-butyl hydroquinone for use only in lubricant formulations for rayon fiber finishing and at a usage level not to exceed 0.1 percent by weight of the lubricant formulations.

Dimethylpolysiloxane.

4-Ethyl-4-hexadecyl morpholinium ethyl sulfate for use only as a lubricant in the manufacture of polyethylene terephthalate fibers specified in paragraph (d)(1) of this section at a level not to exceed 0.03 percent by weight of the finished fibers.

Fatty acid (C<sub>10</sub>-C<sub>18</sub>) diethanolamide condensates.

Fatty acids derived from animal or vegetable fats and oils, and salts of such acids, single or mixed, as follows:

Aluminum.

Ammonium.

Calcium.

Magnesium.

Potassium.

Sodium.

Triethanolamine.

Fatty acid (C<sub>10</sub>-C<sub>18</sub>) mono- and diesters of polyoxyethylene glycol (molecular weight 400-3,000).

Methyl esters of fatty acids (C<sub>10</sub>-C<sub>18</sub>).

Mineral oil.

Polybutene, hydrogenated; complying with the identity prescribed under §178.3740 (b) of this chapter.

Polyoxyethylene (4 mols) ethylenediamine monolauramide for use only in lubricant formulations for rayon fiber finishing and